2014-1713

United States Court of Appeals for the Federal Circuit

UNIVERSITY OF MANITOBA,

Plaintiff – Appellant,

v.

DRAEGER MEDICAL, INC.,

Defendant – Appellee.

Appeal from the United States District Court for the District of North Dakota in case no. 2:13-cv-00048-RRE-KKK, Chief Judge Ralph R. Erickson.

BRIEF FOR DEFENDANT-APPELLEE DRAEGER MEDICAL, INC.

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DECEMBER 1, 2014

CERTIFICATE OF INTEREST

Counsel for the Appellee, Draeger Medical, Inc. certifies the following (use "None" if applicable; use extra sheets if necessary):

1. The full name of every party or amicus represented by me is:

Draeger Medical, Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

Draeger Medical, Inc.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

Draeger Medical, Inc. is a subsidiary of Draeger Medical Systems, Inc., which is a subsidiary of Dräger Medical International GmbH, which is a subsidiary of Dräger Medical GmbH, none of which are publicly traded. Dräger Medical GmbH is a subsidiary of Drägerwerk AG & Co. KGaA, which is publicly traded on the Frankfurt Stock Exchange under the symbol DRW3.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

Wayne A. Jones, Jones IP Group; Dusty S. Vogelpohl, Jones IP Group; Randall S. Hanson, Camrud, Maddock, Olson & Larson, Ltd.; Shannon E. Rogers, Camrud, Maddock, Olson & Larson, Ltd.

December 1, 2014
Date

/s/ Wayne A. Jones
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STATEMENT OF RELATED CASES

There are no other appeals in or from the same civil action in the district court that have previously been before this or any other appellate court.

There is a fully briefed Motion for Exceptional Case Determination and Attorney Fees and Costs filed by Defendant Draeger Medical, Inc., pending in the district court. The University of Manitoba v. Draeger Medical, Inc., Case 2:13-cv-00048-RRE-KKK. Action by the district court on the Motion for Exceptional Case has been stayed until this appeal is resolved.

The Motion for Exceptional Case is the only other matter pending that will be directly affected by this Court's decision on appeal.

STATEMENT OF THE ISSUE

Whether the district court correctly construed the claim limitation "controlled life support conditions" to mean "only patient conditions where there is no patient effort to be taken into consideration."

STATEMENT OF THE CASE

The University of Manitoba ("Manitoba") brought this suit in June 2013 asserting infringement of three related patents, U.S. Patents Nos. 5,647,350; 5,941,841: and 6,027,498 (the '350, the '841, and the '498 patents, respectively), by the Variable Pressure Support ventilation mode of Draeger Medical, Inc.'s ventilators. A28. Manitoba's claims regarding the '841 and '498 patents were dismissed with prejudice after the district court ordered and Manitoba failed to respond to Draeger's objections that both patents were invalid on their face. A35, 838, & 839.

On Draeger's suggestion that all claims pending under the remaining '350 patent could be disposed of by a ruling on the meaning of merely one claim term, "controlled life support conditions," the district court held a claim interpretation hearing on that term. In June 2014 the court issued its Claim Construction Order finding "controlled life support conditions" to mean "only patient conditions where there is no patient effort to be taken into consideration." A35.

Responding to Draeger's assertion that continuing the case after the Claim Construction Order would be a violation of Rule 11, in June 2014 Manitoba conceded non-infringement, noting that the Draeger Variable Pressure Support option "***only*** functions when there is patient breathing." A871 & 873 (emphasis in the original). In July 2014 the district court entered judgment against Manitoba but

gave Draeger fourteen days to file its motion for finding of an "exceptional case." A879-880.

Draeger's motion for "exceptional case" was filed in August 2014 and has been fully briefed by the parties. A36-37. The district court has stayed ruling on the motion until after disposition of the present appeal by the Court of Appeals for the Federal Circuit. A885.

COUNTER-STATEMENT OF THE FACTS

I. INTRODUCTION

This is a fact driven case that is readily determined under well settled law. Appellant's brief did not include many of the governing facts, thus necessitating this lengthy counter-statement of facts.

Clarity in disposition of this case rests, first, on the distinct operational duality of medical ventilators. Medical ventilators can alternately operate according to two different principles. A882. The two principles cannot be applied to a patient simultaneously. A882.

Clarity in disposition rests, secondly, on Manitoba's consistent, oft-repeated, and unambiguous disclaimer that its alleged invention only functioned according to the first principle of ventilator operation (discussed below).

II. VENTILATOR BACKGROUND

According to the first principle a ventilator operates when a patient is not making any effort to breathe (such as in instances of trauma or deep sedation) and the ventilator completely controls the breathing of the patient. A882. Since there is no patient breathing effort, the ventilator completely controls the rate (timing) and volume of each breath provided to the patient. For purposes of discussion this is termed "controlled ventilation."

According to the second principle a ventilator can function to support the breathing of a patient who is making efforts to breath. A882. In this operational modality the ventilator takes into consideration the breathing effort of the patient, such as the timing of each breath (the point when the patient initiates inhalation) and the degree of inhalation accomplished by the patient's own efforts, and then provides supplemental ventilator support in conjunction with the patient breathing effort to ensure sufficient oxygenation of the patient's lungs. A802-804. For purposes of discussion this is termed "assisted ventilation."

Assisted ventilation modes are often used to wean patients off ventilation. These modes allow the patient to initiate her/his own breath and inhale to her/his best capacity while the ventilator provides whatever further assistance the patient needs for complete lung oxygenation. Since the patient does as much breathing work as she/he is able, the weaning modes help the patient redevelop breathing strength until the patient can breathe without ventilation support. A779-780.

The claimed invention of the '350 patent functions in accord with the first mentioned principle of ventilation – controlled ventilation. It applies in instances where the patient is not making any efforts to breath and the ventilator "wholly controls" the breathing of the patient. A19, 607, & 621. It dictates the rate (timing)

of each breath and the volume of each breath forced into the lungs of a patient who is not breathing on his/her own. A607-611 & 625.

The alleged novelty of the ‘350 patent centers around its method of varying the rate and volume of the breaths it applies to the patient who is not making breathing efforts. A609. It administers this breathing according to a predetermined pattern of breathing that, generally, is obtained by recording the actual breathing of a healthy mammal over some period of time (the actual breathing of the healthy mammal having a natural variation from breath to breath both in rate (timing) and volume). A609. The predetermined pattern of healthy breathing is then played back (often in a looped playback) and applied to the patient, breath by breath through the pattern – the timing and the volume of each breath being dictated by the timing and volume of the corresponding breath of the predetermined pattern. A79 & 83.

As outlined below, during prosecution Manitoba made it absolutely clear that its system of controlled ventilation only applied in circumstances where there was no patient breathing effort. A607-611. During prosecution, Manitoba added the case-dispositive element “during controlled life support conditions” to each of its claims in response to a rejection based on the prior art U.S. Patent No. 4,448,192 (the “Stawitcke patent”). A605-606.

The Stawitcke patent, in some degrees similar to the '350 patent, also taught a ventilator that provided varied breathing to patients. However, the Stawitcke ventilator operated in circumstances where the patient was initiating her/his own breaths and the ventilator provided (varied) assistance to each of the patient's own breaths to ensure adequate oxygenation of the lungs. A608 & 803. The Stawitcke ventilator took into consideration the timing and degree of patient breathing effort before providing its varied breathing assistance to each breath. A608 & 805.

To distinguish Stawitcke, Manitoba added the elements "during controlled life support conditions" and "predetermined" to each of its claims. A605-606. It also discussed each new term. Further it clearly defined and limited the meaning of "controlled life support conditions." Manitoba argued (in distinguishing Stawitcke):

> "In contrast [to Stawitcke], in the present invention, the ventilator is operating **during controlled life support conditions where there is no patient effort to be taken into consideration**."

A610-611 (emphasis added).

It is precisely this definition provided by Manitoba and upon which the Stawitcke rejection was overcome that the district court ruled was the proper meaning of "controlled life support conditions." Further, it is precisely this definition provided by Manitoba itself that Manitoba now asks this Court to ignore.

Draeger's accused "Variable Pressure Support" ("VPS") option, in all relevant respects relating to "controlled life support conditions," functions like the Stawitcke device. It ONLY can be operated according to the second principle of ventilation mentioned above – assisted ventilation. The VPS option ONLY functions when there is patient breathing effort (such as when a patient initiates her/his own breath). Once it detects the patient's effort to initiate a breath, the VPS provides a randomly varying partial assistance to each of the patient's breaths (thus the VPS is termed "Pressure Support" - to support the patient's own breathing). If the Draeger ventilator applying the VPS option detects that the patient has ceased breathing efforts (such as ceasing initiating her/his own breaths) the ventilator immediately alarms out of the VPS mode, ceases VPS operation, and begins an entirely different safety mode of ventilation – one which Draeger terms controlled ventilation. A780.

This Draeger controlled ventilation safety mode operates according to the first principle above and completely controls the breathing (including both rate and volume) of the patient. A780. Manitoba does not assert that the Draeger controlled ventilation safety mode which provides a non-varying controlled ventilation breathing pattern to patients and which far predates Manitoba's patent infringes its patent.

Manitoba's patent claims ONLY apply in circumstances of the first principle above – controlled ventilation. Draeger's accused VPS ventilation ONLY functions in circumstances of the second principle above – assisted ventilation. Draeger's accused VPS ventilation only operates in consideration of patient efforts – in the same way the Stawitcke device operated in consideration of patient efforts. Manitoba unambiguously disclaimed that its patent covers such ventilation under the modality of the second principle and specifically disclaimed it covered ventilation in circumstances where there was patient breathing effort to be taken into consideration as the Stawitcke (and Draeger devices) consider patient effort. Manitoba limited the claims to only cover circumstances in which "the ventilator is operating during controlled life support conditions where there is no patient effort to be taken into consideration." A610-611.

III. THE '350 PATENT PROSECUTION HISTORY

The '350 patent issued from patent application Serial No. 404,464 ("the '464 application"). A39. In response to a restriction requirement, Manitoba elected to prosecute three of the original four[1] claims filed with the '464 application – none of which contained the term "controlled life support conditions". A599. The three claims were eventually amended three separate times before they were allowed by

[1] The original '464 application included four claims. In response to a PTO Restriction Requirement Manitoba cancelled original claim 2 and continued prosecution on claims 1, 3, and 4 which in amended form eventually issued as claims 1, 2, and 3, respectively, of the '350 patent. A599.

the patent office. Since the amendments to each of the three claims were virtually identical in form, this memorandum discusses only claim 1 in detail.

Table 1, below, shows the progression of the amendments to issued claim number 1.

TABLE 1

As Filed: 3/15/1995	First Amendment	Second Amendment	Third Amendment
A method of controlling flow of a biological fluid to an organ, which comprises:	A method of controlling flow of a biological fluid to an organ during controlled life support conditions, which comprises:	A method of controlling flow of a biological fluid to an organ during controlled life support conditions, which comprises:	A method of controlling flow of a biological fluid to an organ during controlled life support conditions, said biological fluid being the primary source of fluid to sustain life support to an organ, wherein said method which comprises:
establishing a pattern of variations over time of instantaneous changes in flow of a biological fluid to an organ of a mammalian species,	establishing a predetermined pattern of variations over time of instantaneous changes in flow of a biological fluid to independently-functioning normal organ of a mammalian species,	establishing a predetermined pattern of variations over time of instantaneous changes in flow of a biological fluid to an independently-functioning normal organ of a mammalian species,	establishing a predetermined pattern of variations over time of instantaneous changes in flow of a biological fluid to an independently-functioning normal organ of a mammalian species,
generating a variable control parameter for regulation of flow of said biological fluid to an organ in accordance with said pattern, and	generating a variable control parameter for regulation of flow of said biological fluid to an organ during controlled life support conditions in accordance with said predetermined pattern, and	generating a variable control parameter for regulation of flow of said biological fluid to an organ during controlled life support conditions in accordance with said predetermined pattern, and	generating a variable control parameter for regulation of flow of said biological fluid to an organ during controlled life support conditions in accordance with said predetermined pattern, and
controlling said flow of said biological fluid to said organ in accordance with said variable control parameter	controlling said flow of said biological fluid to said organ during controlled life support conditions in accordance with said variable control parameter	controlling said flow of said biological fluid to said organ during controlled life support conditions in accordance with said variable control parameter to provide a variable flow of said biological fluid to the organ during controlled life support conditions which mimics the normal flow of said biological fluid to a normal organ.	controlling said flow of said biological fluid to said organ during controlled life support conditions in accordance with said variable control parameter to provide a variable flow of said biological fluid to the organ during controlled life support conditions which mimics the normal flow of said biological fluid to a normal organ.

It was in the First Amendment that Manitoba added the term "controlled life support conditions" and specifically distinguished what was covered by the (then) amended claims from the Stawitcke ventilator which apparently did not operate under "controlled life support conditions." A605-606. The Second and Third Amendments were made to distinguish the claims from a different prior art patent, U.S. Patent No. 4,584,996 (the "Blum" patent), and dealt not with "controlled life support conditions" but with the type of flow and constitution of the gases provided to the patient. A618-620 & 634.

A. <u>The Stawitcke Rejection</u>

In the First Office Action on the merits, the PTO rejected all three pending claims as obvious over the Stawitcke patent. A601-602. Stawitcke disclosed a ventilator which, among other things, focused on a ventilation system which accommodated patient breathing efforts:

> A prime concern of any ventilator is accommodation to patient effort. Accommodation to patient effort, or control by the patient, is defined primarily as synchronization of the ventilator's inhale and exhale phases with the phases of the patient's efforts. Secondarily it means the ability to deliver air at the rate desired by the patient. In other words, the ventilator with patient effort accommodation allows the patient some control over the ventilator's operations.

A802.

Stawitcke explained that the type of ventilator it described, by detecting and responding to patient breathing activity, provided a method

> of providing partial assistance to be used as a mode of therapy or for weaning patients from a ventilator. The assistance is provided at the end of each breath initiated by the patient. The amount of assistance is either set by the clinician or automatically optimized by the ventilator . . . . Partially assisting every breath has the advantage of allowing the patient to gradually take over the work of breathing in a more physiological manner than intermittent mandatory ventilation . . . .

A804.

Stawitcke taught that its system could be used in "weaning patients from a ventilator" with a varying amount of ventilator assistance provided to the patient "at the end of each breath initiated by the patient." A805.

Manitoba did not contest the rejection of its claims by the PTO based on Stawitcke but elected instead to amend its pending claims and distinguish the amended claims from the Stawitcke teachings. A605-606. In its First Amendment, Manitoba amended the claims to add the element "during controlled life support conditions" and the word "predetermined" to the claims. Manitoba's amendment to claim 1 in the First Amendment provided:

> 1. A method of controlling flow of a biological fluid to an organ <u>during controlled life support conditions</u>, which comprises:

> establishing a predetermined pattern of variations over time of instantaneous changes in flow of a biological fluid to an independently-functioning normal [an] organ of a mammalian species,
>
> generating a variable control parameter for regulation of flow of said biological fluid to an organ during controlled life support conditions in accordance with said predetermined pattern, and
>
> controlling said flow of said biological fluid to said organ during controlled life support conditions in accordance with said variable control parameter.

A605-606.

The term "controlled life support conditions" was not found and was not used in the '464 specification or prosecution until this First Amendment. Inasmuch as the term, or any variant of it, was not found in the specification, the term certainly was not defined in the specification. To provide meaning to the term and to distinguish its newly amended claims from the Stawitcke prior art, Manitoba explained an important detail about what it meant by "controlled life support conditions." In the First Amendment, Manitoba offered the following explanations and distinctions:

> The Stawitcke device as relied on by the Examiner is concerned primarily with the weaning type of ventilator which provides assisted ventilation to a patient rather than the present invention which is concerned with ventilation **during controlled life support conditions.**

A608 (emphasis added).

> [The Stawitcke] operation is quite different from the operation in the present invention, where the ventilator is operated **during controlled life support conditions** and not under weaning conditions … A (emphasis added)

A609 (emphasis added).

> What is described in Stawitcke in Col. 5 is how the system accommodates patient effort while still maintaining the required target volume … In the present invention, **there is no patient effort to be taken into consideration** and the variation in respiratory rate and tidal volume is predetermined from a pattern taken from a healthy mammal. A. (emphasis added)

A610 (emphasis added).

> It is clear, therefore, that the Stawitcke reference is concerned with quite different circumstances from the present invention. As already noted, the Stawitcke reference is concerned primarily with the weaning type of ventilator wherein gas flow to the patient is controlled … to the weaning patient **while taking into account patient effort.** In the absence of patient effort, the system described by Stawitcke will deliver a monotonously regular tidal volume and respiratory rate according to the preset values programmed by the doctor.
>
> In contrast, in the present invention, the ventilator is operating during controlled life support conditions where **there is no patient effort to be taken into consideration.** Rather than provide a monotonous flow of gas to the patient, a variable flow is provided in accordance with a predetermined pattern of instantaneous respiratory rate and tidal volume which is established from the healthy lungs of a mammal.

A610-611 (emphasis added).

Although there is no teaching in the ‘350 patent specification as to the totality of the meaning of “controlled life support conditions” it is undeniable that Manitoba twice and unambiguously declared that during “controlled life support conditions” as used in each of its claims “there **is no patient (breathing) effort to be taken into consideration**.”

This district court held that “controlled life support conditions” means “only patient conditions where there is no patient effort to be taken into consideration.” A23.

Manitoba now suggests that this clear definition and disclaimer, made during prosecution to obtain allowance of the claims, should be disregarded during litigation to enforce the claims. Manitoba now argues that another term (“primary source”) added in later amendments to the claims controls the meaning of “controlled life support conditions” and actually negates the definition of the term “controlled life support conditions” explicitly set out by Manitoba in the First Amendment. As will be shown hereafter, Manitoba’s currently proposed definition of “controlled life support conditions” actually replaces the term with the meaningless phrase “any patient conditions.”

The other term, “primary source,” was added to the claims in response to rejections based on the Blum prior art.

B. The First Blum Rejection

In response to Manitoba's First Amendment, the PTO issued a Second Office Action rejecting the amended claims of the '464 application – this time on the basis of the Blum patent. A612. The Blum patent did not teach a typical ventilator (as did Stawitcke). Instead Blum taught a typical nasal cannula for providing patients (who were already breathing) with supplementary oxygen. Rather than simply provide a steady flow of oxygen through the cannula, as previous oxygen cannula provided, Blum disclosed a variation in flow over time of the oxygen through the cannula. A813.

Manitoba contends that its amendments made in response to the Blum rejection somehow affect the meaning of the term "controlled life support conditions." However, Blum, like Stawitcke, taught a system that was in use with patients who were initiating their own breaths – patients who were making breathing efforts. A813. Recognizing this, and importantly, the Examiner pointed out that the Blum reference did not involve "controlled life support conditions." A614. Consequently, there is no link between amendments made to overcome Blum and the term "controlled life support conditions" that was already in the claims. Again, the Blum cannula was administered to a patient who was regularly breathing on her/his own and the cannula provided supplemental oxygen to the patient. The examiner stated:

> Claims 1, 3, and 4 are rejected . . . as being unpatentable over Blum. Blum discloses a method and apparatus for: establishing a predetermined pattern of variation over time of flow of biological fluid (oxygen) to an independently-functioning normal lung [and other features of the claims] . . . . . **Blum does not teach "controlled life support conditions**," the use of the method of Blum in any of a variety of patient care settings would have been obvious to one having ordinary skill in the art depending on a wide variety of patient care criteria.

A614 (emphasis added).

In response to the Second Office Action, Manitoba provided another amendment (the "Second Amendment") to the claims to distinguish them from the Blum patent. This amendment had to do with a "variable flow … which mimics normal flow" – it had nothing to do with "controlled life support conditions".

> 1. A method of controlling flow of a biological fluid to an organ during controlled life support conditions, which comprises:
>
> establishing a predetermined pattern of variations over time of instantaneous changes in flow of a biological fluid to an independently-functioning normal [an] organ of a mammalian species,
>
> generating a variable control parameter for regulation of flow of said biological fluid to an organ during controlled life support conditions in accordance with said predetermined pattern, and
>
> controlling said flow of said biological fluid to said organ during controlled life support conditions in accordance with said variable control parameter <u>to provide a variable flow of said biological fluid to the</u>

> organ during controlled life support conditions which mimics the normal flow of said biological fluid to a normal organ.

A618-619.

In support of this Second Amendment patentee confirmed the examiner's understanding of "controlled life support conditions" as well as the examiner's conclusion that Blum did not teach "controlled life support conditions":

> The species under consideration herein is a mechanical ventilator which in **a controlled life support scenario, wholly controls the flow of ventilating gas to the lungs of the patient under life support**. In the Office Action, the Examiner concedes that the Blum reference does not teach such controlled life support conditions but nevertheless considers that the use of Blum's method in any of a variety of patient care settings would have been obvious to one of ordinary skill in the art . . . .
>
> It is submitted that the procedure and apparatus of the present invention differ from the Blum procedure and apparatus.

A621-622 (emphasis added).

This explanation is entirely consistent with and confirms Manitoba's earlier explanation (in its First Amendment) of "controlled life support conditions." In this explanation there is no patient effort to be taken into consideration since the mechanical ventilator "wholly controls the flow of ventilating gas to the lungs of the patient." It also confirms that Manitoba's Second Amendment is to address elements

or features other than the term "controlled life support conditions" since no challenge to "controlled life support conditions" is presented by the Blum patent.

C. The Second Blum Rejection

After this Second Amendment, the Examiner still rejected the pending claims over the Blum patent. In a resulting telephone interview (on July 20, 1996) with the Examiner, an agreement was reached in which an amendment would be entered to further distinguish the claims over the Blum patent. A628. This "Third Amendment" provided:

> 1. A method of controlling flow of a biological fluid to an organ during controlled life support conditions, said biological fluid being the primary source of fluid to sustain life support to an organ, wherein said method which comprises:
>
> establishing a predetermined pattern of variations over time of instantaneous changes in flow of a biological fluid to an independently-functioning normal [an] organ of a mammalian species,
>
> generating a variable control parameter for regulation of flow of said biological fluid to an organ during controlled life support conditions in accordance with said predetermined pattern, and
>
> controlling said flow of said biological fluid to said organ during controlled life support conditions in accordance with said variable control parameter to provide a variable flow of said biological fluid to the organ during controlled life support conditions which

> mimics the normal flow of said biological fluid to a normal organ.

A634.

The Examiner Interview Summary Record states that "Blum teaches oxygen (biological fluid) as a secondary source. Agreement was made to amend claims 1, 3, and 4 – to have the biological fluid as the primary source of fluid to sustain life. This Amendment to Claims 1, 3, and 4 will put this claim (sic) in condition for allowance." A628. Thus the purpose of the Third Amendment was to distinguish the claims over Blum's providing supplemental oxygen to a patient via a cannula (which was not the "primary source" of fluid to sustain life). This amendment had nothing to do with "controlled life support conditions."

Upon entry of the Third Amendment the pending three claims were allowed and the '350 patent issued. A633.

IV. DRAEGER VARIABLE SUPPORT OPTION

The accused Draeger ventilator has several modes and can alternately function in a "controlled ventilation" mode or an "assisted ventilation" mode. The Variable Pressure Support option of the Draeger ventilators ONLY functions when there is patient effort to breath. When VPS is applied to the patient no assistance is provided to the patient until the patient makes an effort to breath and then the VPS provides a

supplemental breathing assistance for the already initiated breath. After the patient exhales a completed breath VPS waits until the patient has initiated another breath before it again provides breathing assistance for that next breath.

If a predetermined time passes without the patient initiating her/his own breath, the Draeger ventilator alarms out of VPS mode and immediately begins dictating both the rate and volume of each breath in a "controlled ventilation" safety mode with values already preset for the patient by the care-giver. This is necessary to guarantee the oxygenation of the patient lungs in circumstances when the patient has ceased to initiate her/his own breaths. The controlled ventilation mode applies a monotonous repetition of identical breaths to the patient for as long as that mode is employed – which will be until if and when a care-giver manually changes the mode of ventilation being applied. Thus the VPS option simply will not operate unless there is patient breathing effort. Manitoba has conceded that VPS "***only*** functions when there is patient breathing." A873 (emphasis in the original).

Manitoba distinguished the Stawitcke prior art ventilator on precisely this same ground:

> In the absence of patient effort, the system described by Stawitcke will deliver a monotonously regular tidal volume and respiratory rate according to the preset values programmed by the operator.

> In contrast, in the present invention …. Rather than provide a monotonous flow of gas to the patient, a variable flow is provided in accordance with a predetermined pattern of instantaneous respiratory rate and tidal volume which is established from the healthy lungs of a mammal.

A610-611.

An additional point of similarity between the accused Draeger VPS option and the Stawitcke ventilator is that the VPS option is particularly recommended in treatment protocols to wean patients off ventilation. A779-780. Yet, Manitoba additionally distinguished its "controlled life support conditions" from the Stawitcke prior art ventilator with the argument that Stawitcke was a "weaning ventilator" – a ventilator configured to assist with breathing while the patient over time develops the ability to breath entirely on her/his own – and thus be "weaned" from ventilation:

> The Stawitcke device as relied on by the **Examiner is concerned primarily with the weaning type of ventilator** which provides assisted ventilation to a patient **rather than the present invention which is concerned with ventilation during controlled life support conditions.**

A608 (emphasis added).

Further, Manitoba argued that the Stawitcke

> operation is quite different from the operation in the present invention, where the ventilator is **operated during controlled life support conditions and not under weaning conditions** …

A609 (emphasis added).

Manitoba's arguments that operating a "weaning ventilator" to provide assisted ventilation is "quite different" from a ventilator operated under "controlled life support conditions" further clarifies the meaning of "controlled life support conditions."

SUMMARY OF THE ARGUMENT

This case presents a simple legal question with a stunning lack of complicating factors. Unfortunately for Appellant, it is a question that has been clearly and consistently answered by this Court. It is the question of whether a patentee can avoid a specific claim limitation and accompanying unambiguous disclaimer made during prosecution of its patent claims in later litigation attempting to enforce the same patent claims.

The term "controlled life support conditions" is not found in the '350 specification. The term has no plain meaning and does not have an ordinary and customary meaning to those of skill in the art.

The term "controlled life support conditions" was first introduced into the '350 prosecution history with the First Amendment to overcome a rejection based on Stawitcke. Stawitcke taught a ventilator that took into consideration patient breathing effort. The First Amendment advanced consistent and repeated unambiguous explanations that "controlled life support conditions" were conditions "where there is no patient effort to be taken into consideration

Applying the fundamental canons of claim construction confirms that the district court's construction of "controlled life support conditions" is correct.

The doctrine of prosecution disclaimer mandates that the district court's construction of "controlled life support conditions" is correct.

Contrary to Manitoba's assertion, the term "primary" was added to the claims in response to a rejection based on Blum which both the examiner and Manitoba admitted did not teach "controlled life support conditions." The term "primary" properly has no negating effect on Manitoba's disclaimer of the claims to only "conditions in which there is no patient effort to be taken into consideration."

ARGUMENT

I. Application of the Canons of Claim Construction to the Facts Confirm the District Court was Correct

A. General Rules of Claim Construction

Claim construction inquiry begins with the intrinsic evidence, which includes the claims, the specification, and the prosecution history. See, e.g., Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005). The words of a claim "are generally given their ordinary and customary meaning." Phillips, 415 F.3d at 1312-1313. The "ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill on the art in question at the time of the invention..." Id. A "person of ordinary skill is deemed to read the claim terms in the context of the entire patent, including the specification and prosecution history." Computer Docking Station Corp. v. Dell, Inc., 519 F.3d 1366, 1378-1379 (Fed. Cir. 2008), citing Phillips, 415 F. 3d at 1313.

In instances such as the present in which there is no ordinary and customary meaning to the claim term, "the prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." Id. at 1317. As stated by the court in Vitronics Corp. v. Conceptronics, Inc., 90 F.3d 1576 (Fed. Cir. 1996), "the court may also consider the prosecution history of the patent, if in evidence. This

history contains the complete record of all the proceedings before the Patent and Trademark Office, including any express representations made by the applicant regarding the scope of the claims. As such, the record before the Patent and Trademark Office is often of critical significance in determining the meaning of the claims." Id. at 1582 (citations omitted).

Further, "explicit statements made by a patent applicant during prosecution to distinguish a claimed invention over prior art may serve to narrow the scope of a claim." Vitronics, 90 F.3d at 1582. Particularly, "[t]he doctrine of prosecution disclaimer 'protects the public's reliance on definitive statements made during prosecution' by 'precluding patentees from recapturing through claim interpretation specific meanings [clearly and unmistakably] disclaimed during prosecution". Computer Docking, 519 F.3d at 1374-75.

B. There is No Ordinary and Customary Meaning to "Controlled Life Support Conditions"

There is no ordinary and customary meaning to "controlled life support conditions." The ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill on the art in question at the time of the invention. Manitoba has never suggested that there is an ordinary and customary meaning. Neither has Manitoba ever offered a single piece of evidence as to the ordinary and customary meaning of the term from a person having ordinary skill in the art.

Draeger's ventilation expert, Dr. Edward Sherren, declared that the term "is not customarily used in describing a patient condition during ventilation and does not have an ordinary meaning to those skilled in the field of ventilation and anesthesiology." A883. Manitoba never challenged this fact and has never contended that there is an ordinary or customary meaning to the term.

C. The Specification Does Not Define the Term "Controlled Life Support Conditions"

Neither the term "controlled life support conditions" nor any variant of it is found in the specification. Indeed the term was not introduced into the record until Manitoba's First Amendment to the '350 claims.

Manitoba has not offered any evidence that "controlled life support conditions" is defined in the specification. The most Manitoba has suggested is to point to a vague reference of "healthy patients" being ventilated[2]. But, as found in Computer Docking, supra, "the specification of the [patent] does not provide an express definition of [the disputed term] that would override or make the distinctions in the prosecution history ambiguous." Computer Docking, 519 F.3d at 1378.

[2] The inapplicability of Manitoba's argument based on "healthy patients" is discussed herein below in section III (b).

D. The Prosecution History Defines the Term "Controlled Life Support Conditions"

Although there is no ordinary and customary meaning to the term and it is not found in the specification, in the prosecution Manitoba provided a clear and unambiguous meaning for "controlled life support conditions." Manitoba repeatedly defined the term as a circumstance or scenario in which "there is no patient effort to be taken into consideration." See, e.g., A610 & 611.

When Manitoba first introduced the term "controlled life support conditions" to the '350 record by adding it to each of the claims, Manitoba also specified a clear limitation to the meaning of the term. Manitoba elected this specifically defined limitation to distinguish the claims from the Stawitcke prior art ventilator. Stawitcke was very clearly a ventilator operating in an assistive ventilation mode where the patient initiated her/his own breaths.

The Stawitcke objectives included accommodation of patient breathing effort. Stawitcke described this as:

> Accommodation to patient effort, or control by the patient, is defined primarily as synchronization of the ventilator's inhale and exhale phases with the phases of the patient's efforts. Secondarily it means the ability to deliver air at the rate desired by the patient. In other words, the ventilator with patient effort accommodation allows the patient some control over the ventilator's operations.

A802.

Stawitcke provided a ventilation method:

> of providing partial assistance to be used as a mode of therapy or for weaning patients from a ventilator. The assistance is provided at the end of each breath initiated by the patient. The amount of assistance is either set by the clinician or automatically optimized by the ventilator . . . . Partially assisting every breath has the advantage of allowing the patient to gradually take over the work of breathing in a more physiological manner than intermittent mandatory ventilation . . . .

A804.

Manitoba elected to distinguish its claims from the Stawitcke ventilator by adding two terms to the claims: "predetermined" and "during controlled life support conditions". A605-606. Both elements are clear limitations to the claims. Both were defined in Manitoba's arguments accompanying the First Amendment.

In its use of the term "controlled life support conditions" to distinguish Stawitcke, Manitoba stated:

> The Stawitcke device as relied on by the Examiner is concerned primarily with the weaning type of ventilator which provides assisted ventilation to a patient **rather than** the present invention which is concerned with ventilation **during controlled life support conditions.**

A608 (emphasis added).

And,

> [The Stawitcke] operation is quite different from the operation in the present invention, where the ventilator is

> operated **during controlled life support conditions** and not under weaning conditions….

A609 (emphasis added).

Manitoba distinguished Stawitcke from its alleged invention as a circumstance which took into account patient effort:

> It is clear, therefore, that the Stawitcke reference is concerned with **quite different circumstances from the present invention.** As already noted, the Stawitcke reference is concerned primarily with the weaning type of ventilator wherein gas flow to the patient is controlled … to the weaning patient **while taking into account patient effort.**

A610 (emphasis added).

Manitoba stated that in the circumstances of application of its alleged invention "there is no patient effort to be taken into consideration":

> What is described in Stawitcke in Col. 5 is how the system accommodates patient effort while still maintaining the required target volume … In the present invention, **there is no patient effort to be taken into consideration** and the variation in respiratory rate and tidal volume is predetermined from a pattern taken from a healthy mammal.

A610 (emphasis added).

Finally, Manitoba unequivocally defines "controlled life support conditions" as those where "there is no patient effort to be taken into consideration":

> In contrast, in the present invention, the ventilator is operating during controlled life support conditions where **there is no patient effort to be taken into consideration.**

A610-611 (emphasis added).

The prosecution history is absolutely clear that Manitoba limited "controlled life support conditions" to be "conditions where there is no patient effort to be taken into consideration."

i. The Second and Third Amendments Made in Response to the Blum Rejections Do Not Affect the Meaning of "Controlled Life Support Conditions"

Both the Examiner and Manitoba acknowledged that the Blum patent did not present a circumstance of "controlled life support conditions." Consequently, there was no reason for the Second and Third Amendments to have any effect on that element. Additionally, the actual amendments made were to specify providing a "variable flow … which mimics normal flow" and the "biological fluid being the primary source of fluid" which distinguished the Blum cannula device which only provided a supplemental oxygen supply to a patient who was carrying out her/his own breathing. The amendments in response to the Blum rejection had nothing to do with whether the patient was or was not initiating her/his own breaths.

However, both the examiner's comments and Manitoba's response confirmed the definition of "controlled life support conditions" found in the district court construction. First, the examiner confirmed his understanding of "controlled life

support conditions" with his conclusion that Blum "does not teach 'controlled life support conditions….'"

> Claims 1, 3, and 4 are rejected . . . as being unpatentable over Blum. Blum discloses a method and apparatus for: establishing a predetermined pattern of variation over time of flow of biological fluid (oxygen) to an independently-functioning normal lung [and other features of the claims] . . . . . **Blum does not teach "controlled life support conditions**," the use of the method of Blum in any of a variety of patient care settings would have been obvious to one having ordinary skill in the art depending on a wide variety of patient care criteria.

A614 (emphasis added).

Second, Manitoba confirmed that Blum does not teach controlled life support conditions, thus acknowledging its mutual understanding with the examiner of the definition of the term.

> The species under consideration herein is a mechanical ventilator **which in a controlled life support scenario, wholly controls** the flow of ventilating gas to the lungs of the patient under life support**. In the Office Action, the Examiner concedes that the Blum reference does not teach such controlled life support conditions** ….

A621 (emphasis added).

Importantly, in the above quote, Manitoba states that in a "controlled life support scenario" the ventilator "wholly controls the flow of ventilating gas to the lungs of the patient under life support." This is an exact quote from Manitoba's characterization in the First Amendment and confirms again Manitoba's consistent

definition that during controlled life support conditions there "is no patient effort to be taken into consideration." Clearly, if the patient is initiating her/his own breaths then it is impossible that the ventilator is "wholly" controlling the flow of ventilating gas to the lungs of the patient.

Manitoba seeks to import meaning to "controlled life support conditions," from the term "primary" added in its Third Amendment regarding the source of fluids to the lungs. However, each of "controlled life support conditions" and "primary" were separately added in separate amendments to distinguish over separate pieces of prior art which, themselves, taught completely different features and were the basis for rejections based on completely different technical issues. With the Blum rejections and consequent amendments, the prosecution shifted from focus on "controlled life support conditions" to the source of fluids. Not only is there no logical connection between the two terms, but the attempt to impute meaning from a later amendment made in response to a rejection on a second piece of prior art is a scenario already faced and rejected by this Court:

> "What QSound fails to acknowledge, however, is that the amendment and accompanying remarks were made for the purpose of overcoming the outstanding rejection based on the British patent. **That the prosecution shifted to a different focus does not blunt the impact of those remarks made to overcome the prior rejection**."

Desper v. Spatializer, 157 F.3d 1325, 1336 (Fed. Cir. 1998).

So, too, in the present instance, the fact that the prosecution shifted to a different focus (Blum) does not blunt the impact of Manitoba's remarks made to overcome the Stawitcke rejection.

It is important to note that any amendments made to the claims in response to the Blum rejection(s) were not made to modify Manitoba's earlier positions on the meaning of "controlled life support conditions". They were made to address and distinguish other terms or elements of the claims that were taught by Blum. The case law teaches that the purpose of the review of the prosecution history is to identify what the examiner and the applicant understood the alleged invention to be. Phillips, 415 F.3d at 1317. Clearly here the examiner did not consider any response to the Blum reference to relate to "controlled life support conditions" and Manitoba conceded the same.

E. Extrinsic Evidence

Although extrinsic evidence is in general less useful than intrinsic evidence, courts are authorized "to rely on extrinsic evidence, which 'consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.'" Vitronics at 1582 (quoting Markman v. Westview Instruments, Inc., 52 F.3d 967, 980 (Fed. Cir. 1995)). "[E]xtrinsic evidence can help educate the court regarding the field of the invention and can help

the court determine what a person of ordinary skill in the art would understand claim terms to mean…." Phillips, 415 F.3d at 1319.

Draeger introduced evidence from Draeger's expert, Dr. Edward Sherren, to show what a person having ordinary skill in the art would understand the term "controlled life support conditions" to mean. A883. Dr. Sherren confirms that "to the best of my knowledge the term 'controlled life support conditions' is not customarily used in describing a patient condition during ventilation and does not have an ordinary meaning to those skilled in the field of ventilation and anesthesiology." A883. This further confirms that the court cannot turn to those of ordinary skill in the art for an established definition of the term. It should be noted that Manitoba has offered no evidence as to what a person having ordinary skill in the art would consider "controlled life support conditions" to mean. Nor has Manitoba ever challenged or rebutted Dr. Sherren's testimony.

Dr. Sherren also offered further support that "controlled life support conditions" means a condition in which "there is no patient effort to be taken into consideration." Dr. Sherren offered his opinion as follows:

> With respect to ventilation, if one were to propose the term "controlled life support conditions" and characterize it as a condition in which there is no patient effort to be taken into consideration I would conclude that this is a condition in which there is no patient breathing effort.

A883.

As can be seen, the only piece of intrinsic evidence giving meaning to the term "controlled life support conditions" is the prosecution history of the '350 patent, which defines it as "only patient conditions where there is no patient effort to be taken into consideration." This is further supported by the extrinsic evidence offered by Draeger's expert, Dr. Sherren.

In summary, there is no ordinary and customary meaning to the term "controlled life support conditions." The term is not mentioned in the specification. The only mention of the term in the record, is in the prosecution history which provides a repeated and clear definition of the term. All these considerations confirm that the meaning of "controlled life support conditions" is "only patient conditions where there is no patient effort to be taken into consideration."

II. The Law of Prosecution Disclaimer Also Confirms that the District Court was Correct

This case presents a classic instance of prosecution disclaimer. Prosecution disclaimer limits the interpretation of claim terms so as to exclude any interpretation that was unambiguously disclaimed during prosecution. Faced with a rejection of its proposed claims by the patent office, Manitoba did not dispute the rejection but chose to amend its patent claims and distinguish the prior art (Stawitcke) from the amended claims on the basis of the newly added terms to the claims. Moreover, in the same action, Manitoba specifically defined aspects of the newly introduced terms and described how those aspects distinguished the new claims from the prior art. It

is precisely those aspects which distinguish Draeger's device from Manitoba's claims.

Manitoba has sued Draeger for a device that, in all relevant aspects relating to "controlled life support conditions," is exactly like the Stawitcke prior art. Astonishingly, Manitoba has conceded that the Draeger device does not infringe the claims using the definition Manitoba itself provided during prosecution. A873.

In Computer Docking, the Court explained that:

> '[A] patentee may limit the meaning of a claim term by making a clear and unmistakable disavowal of scope during prosecution.' A patentee could do so, for example, by clearly characterizing the invention in a way to try to overcome rejections based on prior art.
>
> …
>
> Claims should not be construed 'one way in order to obtain their allowance and in a different way against accused infringers.'

Computer Docking, 519 F.3d at 1374 (citations omitted).

> The doctrine of prosecution disclaimer 'protects the public's reliance on definitive statements made during prosecution' by 'precluding patentees from recapturing through claim interpretation specific meanings [clearly and unmistakably] disclaimed during prosecution.'

Id., at 1374-1375.

Prosecution disclaimer is a fundamental precept in claim construction. As stated in Omega Engineering, Inc. v. Raytek Corp.:

> The doctrine of prosecution disclaimer is well established in Supreme Court precedent, precluding patentees from recapturing through claim interpretation specific meanings disclaimed during prosecution.
>
> In light of the Court's guidance, we have adopted that doctrine as a fundamental precept in our claim construction jurisprudence. As a basic principle of claim interpretation, prosecution disclaimer promotes the public notice function of the intrinsic evidence and protects the public's reliance on definitive statements made during prosecution.

Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1323-24 (Fed. Cir. 2003) (citations omitted).

Federal Circuit precedents finding prosecution disclaimer are numerous. The authority is clear that "the prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution." Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed. Cir. 1995); see also Ekchian v. Home Depot, Inc., 104 F.3d 1299, 1304 (Fed. Cir. 1997) ("[B]y distinguishing the claimed invention over the prior art, an applicant is indicating what the claims do not cover, he is by implication surrendering such protection."); Alpex Computer Corp. v. Nintendo of America, Inc., 102 F.3d 1214, 1221 (Fed. Cir. 1996) ("[B]ecause Alpex admitted during prosecution that its claims do not cover a video display system based on shift registers as in Okuda, i.e., it argued that a system

based on shift registers is not structurally or functionally equivalent to a RAM based system that can randomly access a single bit, Alpex's claims cannot now be construed to cover the NES, which possesses the same structural and functional traits as Okuda"); Spectrum Int'l, Inc. v. Sterilite Corp., 164 F.3d 1372, 1378 (Fed. Cir. 1998) ("Unambiguous intrinsic evidence in turn provides sufficient input to the rules of claim construction, in particular in this case, the rule that explicit statements made by a patent applicant during prosecution to distinguish a claimed invention over prior art may serve to narrow the scope of a claim."); Vitronics, 90 F.3d at 1582 ("[The prosecution] history contains the complete record of all the proceedings before the Patent and Trademark Office, including any express representations made by the applicant regarding the scope of the claims. As such, the record before the Patent and Trademark Office is often of critical significance in determining the meaning of the claims."); Phillips, 157 F.3d at 871 (Fed. Cir. 1998) ("We read Edmonds' statements during prosecution as requiring that the polymeric product contain a sufficient amount of block copolymer molecules such that the polymeric product may be properly classified as a 'block copolymer.'"); Uship. Intellectual Props., LLC v. U.S., 714 F.3d 1311, 1315 (Fed. Cir. 2013) ("[P]atent applicant's response to a restriction requirement may be used to interpret patent claim terms or as a source of disclaimer.").

What is not numerous, however, are instances as brazen as the present. Manitoba, with absolutely no evidence to support its position, denies applicability of exactly the words it used to define and limit its claims. Further, Manitoba concedes that Draeger does not infringe if the claims mean exactly the words Manitoba itself repeatedly and consistently used during prosecution to limit its claims.

Manitoba stated:

> In the present invention, **there is no patient effort to be taken into consideration**….

A610 (emphasis added).

And

> [I]n the present invention, the ventilator is operating during controlled life support conditions where **there is no patient effort to be taken into consideration**.

A610-611 (emphasis added).

There is no ambiguity in Manitoba's disclaimer. No ambiguities arise from the specification inasmuch as the term is simply not used in the specification. The term is not known to those of skill in the art. Manitoba's disclaimers were consistently the same and repeatedly made. There were no attempts to rescind or modify the disclaimers. Manitoba consistently said that its claimed invention "wholly" controlled the breathing of the patient and that the alleged invention

applied in "circumstances" of "controlled life support conditions where there is no patient effort to be taken into consideration."

The district court did not "create" or "extrapolate" a definition from a complicated prosecution history, instead the court simply adopted the clear and definite words Manitoba consistently and repeatedly used in prosecution to define and limit the term.

The District Court correctly determined, that Manitoba "specifically disclaimed that its patent covers medical situations in which there is a patient under controlled life support conditions and the patient's breathing effort is to be taken into consideration." A23.

III. Manitoba's Arguments Are Without Merit and the District Court Correctly Interpreted the Term

A. The District Court's Construction Relied on the Relevant Portions of the Prosecution History and that History Dictated the Correct Construction

Manitoba asserts that the district court's construction was "gleaned from selective portions of the prosecution history" and further asserts that the construction is inconsistent with the prosecution history when read as a whole. Manitoba Br. 7. Manitoba leads its discussion with citation to inapplicable law and the accompanying statement that "[i]t is well settled that the prosecution history cannot be used to vary the plain language of the claims themselves." Manitoba Br. 12.

However, it is quite clear that the courts do, in instances such as the present, quite regularly vary the plain language of the claims. Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1324 (Fed. Cir. 2003) ('[W]here the patentee has unequivocally disavowed a certain meaning to obtain his patent, the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of the surrender.'); Hockerson-Halberstadt, Inc. v. Avia Group International, Ltd., 222 F. 3d 951 (Fed. Cir. 2000), (holding that an inventor disclaimed the ordinary meaning of a phrase in a patent's claim. The ordinary meaning was supported by the patent's specification, but, during prosecution, the inventor disclaimed the ordinary meaning by giving a narrower, unconventional meaning to distinguish the prior art cited by an examiner. The patent owner contended that the argument should be disregarded as an erroneous interpretation of the claimed invention. To the court, this contention "reduces to a request for a mulligan that would erase from the prosecution history the inventor's disavowal of a particular aspect of a claim term's meaning."

i. The Prosecution History Discussion of “monotonous flow” Confirms the District Court’s Construction

Manitoba asserts that the real prosecution history “distinction” over the Stawitcke patent was the monotony with which such art provided fluids to a patient

rather than whether such systems allowed for patient breathing. Manitoba Br. 13-14. Manitoba cites its First Amendment:

> Rather than provide a monotonous flow of gas to the patient, a variable flow is provided in accordance with a predetermined pattern of instantaneous respiratory rate and tidal volume which is established from the healthy lungs of a mammal.

A611.

However, this citation directly supports the district court's construction – not Manitoba's proposed definition. The citation speaks to the "variable flow" provided by the "predetermined pattern." It will be remembered that the First Amendment provided two amendments to the claims – "controlled life support conditions" and "predetermined" pattern. It is beyond question that the citation above seeks to distinguish Stawitcke on the basis of the added "predetermined" term and not the "controlled life support conditions" term. The district court relied on other statements in the First Amendment that directly spoke to "controlled life support conditions" for the definition of that term. Manitoba's citation and twisted use of this "monotonous flow" reasoning is inaccurate and intellectually disingenuous.

Furthermore, Manitoba's attempt to use "monotonous" is inapposite. The First Amendment statement regarding Stawitcke teachings and "monotonous" is:

> In the absence of patient effort, the system described by Stawitcke will deliver a monotonously regular tidal volume and respiratory rate according to the preset values programmed by the operator.

A610.

The quoted language refers to what Stawitcke would do "in the absence of patient effort." But, Manitoba's argument against Stawitcke was that it operated in conjunction with and took into account patient breathing effort. In other words, Stawitcke was distinguished for what it did when the patient was breathing, not what it did when the patient wasn't breathing ("in the absence of patient effort"). Again, Manitoba's argument is entirely unsupportable by the record.

In another instance, Manitoba proposes an indecipherable argument that the prosecution history regarding Blum does not support the district court's construction. Manitoba Br. 15. Manitoba assembles a jumble of assorted citations regarding "gathering normal breathing data", "variation in flow rate", and "secondary source" and concludes, triumphantly, that "the district court recognized [the Second Amendment] as part of its final claim construction" – for whatever that signifies. Manitoba Br. 15. Apparently, Manitoba implies that the district court in some fashion misapplied the record of the Blum amendments. However, it is entirely unclear how any of these assembled citations and accompanying argument relate to the definition of "controlled life support conditions" or supports Manitoba's

implication. The prosecution history is clear, though that both the examiner and Manitoba acknowledged that Blum did not involve "controlled life support conditions" and that Manitoba in response to the Blum rejection stated that the claimed ventilator "wholly" controlled the breathing of the patient. In such case, the patient could not have been initiating or controlling her/his own breaths – thus there was no patient effort to be taken into consideration.

The district court's construction relied on the portions of the prosecution history relevant to the definition of and limitations applied by Manitoba to the term "controlled life support conditions."

B. The District Court's Construction is Not Inconsistent with the Specification

Manitoba repeatedly cites Phillips for the proposition that the specification "is the single best guide to the meaning of a disputed term." However, it is beyond doubt that the specification is entirely silent as to the term.

Manitoba implies that there is support in the specification for its proposed construction and cites the district court's mistaken reliance on Manitoba's misapplication of a single sentence of the specification. Manitoba Br. 10. The district court stated that "at first blush, the scope of the invention appears to encompass a variety of patient conditions, ranging from situations where there is

some patient breathing effort to no patient breathing effort." A15. The misapplied sentence from the specification sets out:

> Even in healthy patients being ventilated during elective surgery, alterations in gas exchange can be demonstrated.

A79.

Manitoba had extrapolated from this sentence and represented to the district court that:

> In other words, the subject invention is useful in "elective surgery," *i.e.*, when a patient is capable of breathing somewhat on his or her own and the claimed invention is not the sole source of biological fluid. This teaching supports the University's proposed construction.

Manitoba Br. 4.

Manitoba repeated this same reasoning to this Court. Manitoba Br. 12. But the cited sentence from the specification discusses the background of the invention. There is no suggestion that this relates to the claimed invention. It is not clear what a "healthy patient" is, nor the relationship of that patient to "elective surgery." The specification statement suggests that healthy patients can have negative effects from mechanical ventilation. Manitoba provides no evidence supporting its leap in logic that concludes that "healthy patients" in "elective surgery" make "some breathing effort" during ventilation. There is no teaching that the "healthy patient" is spontaneously breathing while on the ventilator. This sentence does not provide

support for the district court's conclusion that at first blush the scope of the invention appears to encompass situations where there is some patient breathing effort. Manitoba has not offered any evidence to support this conclusion to this Court.

It is common knowledge that a "healthy patient" could elect to undergo any number of surgeries in which the patient is heavily sedated to the point of not making any attempt to breath. The sentence from the specification provides absolutely no support for Manitoba's arguments.

Since the specification is entirely silent as to the term "controlled life support conditions" the district court's construction of the term is certainly not inconsistent with the specification.

C. The District Court's Construction is Not Inconsistent with the Plain Language of the Claims

Manitoba asserts that the district court's construction is inconsistent with the plain language of the claims. However, Manitoba never offered any evidence that the term "controlled life support conditions" has a plain meaning. Instead, Manitoba misdirects the Court to the plain meaning of the term "primary." Manitoba offers up extrinsic evidence to show that "primary" does in fact mean primary.

Nothing in the court's construction of "controlled life support conditions" affects the meaning or scope of the term "primary" as used in the claims. Draeger

does not dispute the plain meaning of "primary." However, Manitoba next makes yet another unsupportable leap in logic – asserting that "primary source of fluid" is inconsistent with "no patient effort." Manitoba Br. 11. Manitoba offers no evidence to support this conclusion. Apparently, Manitoba hopes the Court will accept this asserted factual truism simply because Manitoba says it is so. There is absolutely NO evidence or logic to support Manitoba's assertion. It is, as shown below, simply not true.

Draeger contends that "primary source" as used in the claims and under the construction of the district court can mean a primary source. A sole source can be a "primary source". A principal source of more than one sources can be a "primary source."

The district court's claim construction does not limit the possibility of other (secondary) sources of biological fluid to patients in controlled life support conditions. In fact it is known by those having skill in the art that it is possible to have more than one ventilation system attached to a patient during controlled life support conditions. In such circumstances, one ventilator could serve as a primary source of fluid, while one or more other sources could serve as additional (or "secondary") sources. During the Markman Hearing of April 17, 2014, Draeger introduced art that clearly showed such situations. A870. See U.S. Patent No.

6,269,813 ("[A] mechanical ventilator is used to completely take over the patient's breathing function by alternately forcing inflation gas into the lungs and thereafter removing exhalation gas from the lungs … One method of decreasing complications … involves … supplying a secondary source of air into the trachea at a higher velocity but lower volume than the mechanical ventilator.") A817-828; Combined Unilateral High Frequency Jet Ventilation and Contralateral Intermittent Positive Pressure Ventilation, B.A. Morgan, D. Perks, I.D. Conacher, M.L. Paes, Anesthesia, 1987, Volume 42, pages 975-979 (During lung surgery a Fluidor 2 ventilator administered intermittent positive pressure ventilation (IPPV) to the patient's left lung while an Acutronic MK800 ventilator simultaneously administered high frequency jet ventilation on the right lung undergoing a lower lobectomy for lung carcinoma.) A829-833.

Manitoba's constructed argument that "primary source of fluid" is inconsistent with "no patient effort" is an unsupported artifice and, as shown by Draeger's proffered examples, is simply not true. However, Manitoba, with knowledge of the ventilation treatment facts proffered by Draeger has nonetheless soldiered on in the face of facts to propose this mistake to the Court.

The district court invited Manitoba to respond to the art showing multiple sources of ventilation to patients in "controlled life support conditions." A870. Manitoba never responded.

Nothing about the term "primary source" or the plain language of any other term is inconsistent with the district court's construction.

D. Manitoba's Proposed Construction Renders "Controlled Life Support Conditions" Entirely Superfluous

Manitoba asserts that "the district court's construction illegitimately reads the term 'primary' out of the claim." As shown above, this is not true.

However, Manitoba's proposed construction does render the term "controlled life support conditions" superfluous. Manitoba's proposed construction is that the term should mean "any patient condition so long as the biological fluid is the primary source to sustain life support to an organ."

Manitoba offers no step by step analysis and/or evidence supporting the correctness of its proposed definition under the canons of claim construction. Its arguments are only that the district court's construction is wrong.

In fact, Manitoba's proposed interpretation, when written into the claims, shows the absurdity of its proposal. Substituting Manitoba's proposed interpretation

for "controlled life support conditions" in the patent claim would result in a claim that read (in part) as:

> A method of controlling flow of a biological fluid to an organ during [~~controlled life support conditions~~] any patient condition so long as the biological fluid is the primary source to sustain life support to an organ, said biological fluid being the primary source of fluid to sustain life support to an organ …

However, almost all the words of Manitoba's proposal are already in this clause of the claim. The only words which are not redundant are "any patient condition so long as". Thus, deleting the redundancy attendant to Manitoba's proposal, Manitoba's proposed claim would read as:

> A method of controlling flow of a biological fluid to an organ during any patient condition so long as said biological fluid being the primary source of fluid to sustain life support to an organ,

So, Manitoba's proposed construction essentially would eliminate "controlled life support conditions" and replace it with "any patient condition" – a definition that obviously covers EVERY patient no matter what their condition.

Adopting Manitoba's proposed construction would render the term "controlled life support conditions" and all the consistent limiting language of "conditions where there is no patient effort to be taken into consideration" a complete nullity – a result not tolerated under the canons of claim construction. See,

e.g., Becton, Dickinson & Co. v. Tyco Healthcare Group, LP, 616 F.3d 1249 (Fed. Cir. 2010); Cat Tech LLC v. TubeMaster, Inc., 528 F.3d 871(Fed. Cir. 2008); Elekta Instrument S.A. v. O.U.R. Sci. Int'l, Inc., 214 F.3d 1302 (Fed. Cir. 2000).

E. The District Court Correctly Construed "Controlled Life Support Conditions" to Mean "Only Conditions in Which There Is No Patient Effort to be Taken Into Consideration"

The term "controlled life support conditions" is not found in the '350 specification. The term has no plain meaning and does not have an ordinary and customary meaning to those of skill in the art. It was first introduced into the '350 prosecution history with the First Amendment to overcome a rejection based on Stawitcke. Stawitcke taught a ventilator that took into consideration patient breathing effort. The First Amendment advanced consistent and repeated unambiguous explanations that "controlled life support conditions" were conditions "where there is no patient effort to be taken into consideration."

The district court correctly held that "controlled life support conditions" means "only patient conditions where there is no patient effort to be taken into consideration."

CONCLUSION AND STATEMENT OF RELIEF SOUGHT

Draeger respectfully requests that the Court affirm the district court's construction of "controlled life support conditions" as meaning "only patient conditions where there is no patient effort to be taken into consideration."

Respectfully submitted,

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United States Court of Appeals
for the Federal Circuit

University of Manitoba v. Draeger Medical, Inc., 2014-1713

CERTIFICATE OF SERVICE

I, Elissa Matias, being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

Counsel Press was retained by JONES IP GROUP, Attorneys for Appellee to print this document. I am an employee of Counsel Press.

On **December 1, 2014** counsel has authorized me to electronically file the foregoing **Brief for Defendant-Appellee** with the Clerk of Court using the CM/ECF System, which will serve via e-mail notice of such filing to all counsel registered as CM/ECF users, including any of the following:

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December 1, 2014

/s/ Elissa Matias
Counsel Press

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/s/ Wayne A. Jones
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